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510(k) Summary
for the Dale® Medical Products, Inc.
The Dale® ACE* Connector
(*Access Controller for Enteral)
(per 21 CFR 807.92)

OCT 30 2008

1. SUBMITTER/510(K) HOLDER

Dale® Medical Products, Inc.
7 Cross Street
Plainville, MA 02762

Contact Person: Malcolm Card
Telephone: 508-695-9316

Date Prepared: August 6, 2008

2. DEVICE NAME

Proprietary Name: The Dale® ACE (*Access Controller for Enteral) Connector
Common/Usual Name: GI tube connector
Classification Name: Gastrointestinal tubes and accessories

3. PREDICATE DEVICES

- Lopez Valve, K915171

4. DEVICE DESCRIPTION

The Dale® ACE* Connector is a device that is inserted between the enteral tube and the fluid administration tubing or drain receptacle. It is designed to reduce the need for repeated and regular disconnection of the enteral tube from the associated tubing.

5. INTENDED USE

The Dale® ACE* (*Access Controller for Enteral) Connector is indicated for controlling fluid flow into and out of medical tubes while providing for the delivery of enteral formula, syringe irrigation, and liquid medication, without breaking the fluid delivery lines. This closed system protects the healthcare worker from accidental exposure to the patient's gastric fluids.

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6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Dale® Medical Products, Inc. claims substantial equivalence of the Dale® ACE* Connector to the predicate device based on the intended use, fundamental technology, and operation characteristics. A side-by-side comparison of the Dale® ACE* Connector and the cited predicate device is included in the 510(k).

7. PERFORMANCE TESTING

Testing of the Dale® ACE* Connector demonstrates that the device meets design and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 2008

Dale® Medical Products, Inc.
c/o Rosina Robinson, R.N., MEd., RAC
Principal Consultant, Regulatory Services
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K082241
Trade/Device Name: Dale® Medical Products, Inc. Dale® ACE* Connector
(*Access Controller for Enteral)
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: November 4, 2008
Received: November 4, 2008

Dear Ms. Robinson:

This letter corrects our substantially equivalent letter of October 30, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure – New Indications for Use Form

Indications for Use

510(k) Number (if known): K082241

Device Name: Dale® Medical Products, Inc. Dale® ACE* Connector (*Access Controller for Enteral)

Indications for Use:

The Dale® ACE* Connector (*Access Controller for Enteral) is indicated for controlling fluid flow into and out of medical tubes while providing for the delivery of enteral formula, syringe irrigation, and liquid medication, without breaking the fluid delivery lines for up to 30 days. This closed system protects the healthcare worker from accidental exposure to the patient's gastric fluids.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082241